VI. Summary of Safety and Effectiveness K062819

Submitter's name, address, telephone number and contact person:

Bioplate, Inc.
3643 Lenawee Avenue
Los Angeles, CA, 90016
(310) 815-2100
(310) 815-2126 (fax)

Contact Person: Jesus Farinas

DEC - 4 2006

Trade name of Device:

Modified plate design for use in conjunction with the Bioplate® Rigid Bone Plating system for Craniomaxillofacial surgery.

Common Name:

Bone Fixation Plates

Device Classification:

Class 2, 21 CFR 882.5330
GXN

Predicate Devices:

Modified Plate designs for use with the Bioplate® Rigid Fixation Bone plating System for Craniomaxillofacial Surgery (K021864)

Plate designs for use in conjunction with the Bioplate® Rigid Fixation Bone plating System for Craniomaxillofacial Surgery (K992330)

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery (K980983).

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery (K972463).

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery (K953273).

The Bioplate® Titanium Fixation System (K943071).

The Wurzberg Titanium Mini Bone Plates and Bone Screws (K854886) and the Maxillofacial Titanium Micro Set (K854886).

The Synthes Maxillofacial Titanium Micro Set (K912932).

Description of the Device:

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery include a variety of plate configurations for different anatomical applications. Unalloyed commercial pure Grade 1, 2 and 4 titanium, titanium alloy plates as well as titanium alloy screws of varying diameters and lengths are included for fixation of the plates to the craniomaxillofacial tissues.

Intended Use of the Device:

The modified plate designs for use in conjunction with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial surgery are intended for use in the reconstruction of the cranium (skull) following surgical decompression procedures of the posterior fossa or transcervical skull-based approach, with or without duraplasty including but not limited to procedures to treat Chiari I Malformation. The plate designs are also intended for use in non-load bearing fixation, including but not limited to cranial bone fixation. Each device is intended for single use only, and only in conjunction with other titanium and titanium alloy implants.

Comparison of the device's technological characteristics with those of the predicate devices

All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate devices, and any minor differences raise no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bioplate, Inc.
% Mr. Jesus T. Farinas
Director, Quality Assurance/Regulatory/Affairs
3643 Lenawee Avenue
Los Angeles, California 90016

DEC - 4 2006

Re: K062819
Trade/Device Name: Modified plate design for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: September 5, 2006
Received: September 25, 2006

Dear Mr. Farinas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucher MD
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K062819

Device Name: Modified plate design for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery.

Indication for Use:

The modified plate designs for use in conjunction with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial surgery are intended for use in the reconstruction of the cranium (skull) following surgical decompression procedures of the posterior fossa or transcervical skull-based approach, with or without duraplasty including but not limited to procedures to treat Chiari I Malformation. The plate designs are also intended for use in non-load bearing fixation, including but not limited to cranial bone fixation. Each device is intended for single use only, and only in conjunction with other titanium and titanium alloy implants.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Evaluation (ODE)

Prescription Use X OR Over-The Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Barbara Buchman

(Division Sign-Off)
Division of General Restorative,
and Neurological Devices

510(k) Number K062819